REMARKS/ARGUMENTS

Claims 1, 3-5, 7-11, 14 and 17-21 of the present application were examined and were rejected by the Examiner. Claims 1 and 7-11 have been amended, no claims have been canceled and no claims have been added. Applicants request entry of this amendment and reconsideration of the pending claims given the amendments and remarks made herein.

Claim Rejections – 35 USC § 112

Claims 7-11 were rejected under second paragraph of 35 USC § 112 as being indefinite for having insufficient antecedent basis for the term "the balloon" (Office Action, page 2). Claims 7-11, which depend from claim 1, have been amended to depend from claim 5 which recites that the expansible tissue compression element comprises "a balloon" to establish proper antecedent basis. Thus, Applicants respectfully request the rejections be withdrawn.

Claim Rejection – 35 USC § 102

Claims 1, 5, 8-11 were rejected under 35 USC 102(b) as allegedly anticipated by US Patent No. 5,419,765 to Weldon et al. (herein after "Weldon") (Office Action, pages 2-4). Such rejections are traversed in part and overcome in part for the following reasons.

Without conceding the correctness of the rejection and to expedite prosecution, Applicants have amended independent claim 1 to further distinguish the claimed method from the cited reference. Even prior to amendment, claim 1 recited advancing the tubular compression member so that "**a distal end of the expansible tissue compression element** is located within the tissue tract at a **predetermined distance proximal from the wall of the blood vessel** to define a **tissue compression region.**" Claim 1 has now been amended to further recite expanding the expansible tissue compression element within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and compress said tissue over the puncture site, "wherein the **compression element is not in direct contact with the vessel wall** . . ." Support for this amendment can be found throughout the application as filed, and in particular in Paragraphs [0005], [0011], and [0017]-[0018], as well as in Figures 8C-8G of the application as filed.

Advancing the compression member so that a distal tip of the compression member is located a predetermined distance proximal from the vessel wall allows the

compression member to define a tissue compression region such that the compression member compresses subcutaneous tissue over the puncture site without directly contacting the vessel wall, as shown for example in a detail of Figure 8F shown below. This feature allows coagulant formulation and reduces the chances of disrupting the coagulant by contacting the vessel wall with the compression member (Paragraphs [0017]-[0018]). This is particularly advantageous since direct contact with the outside surface of the wall may result in excessive compression causing herniation of the balloon through the puncture site or disruption of the coagulant when the expandable member is removed from the vessel wall.

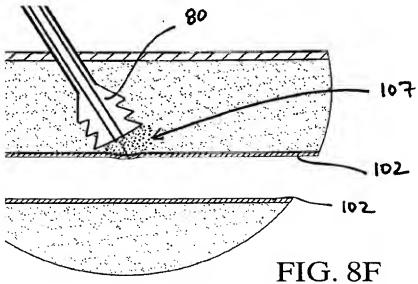


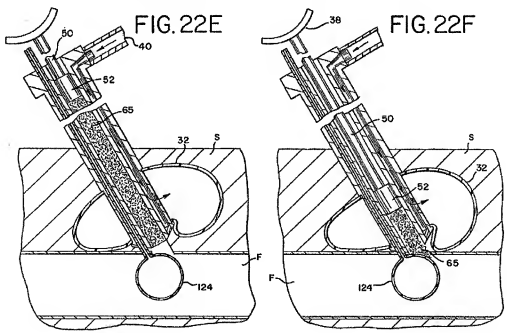
FIG. 8F

Anticipation of a claim under 35 USC § 102 requires that each and every element as set forth in the claim be described in a single prior art reference, and the identical invention must be shown in as complete detail as is contained in the claim (emphasis added). MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully maintain that Weldon fails to disclose each and every element of the method of claim 1, in particular the above bolded elements.

Weldon fails to disclose advancing a tissue compression member over an inserted locating member so that a distal end of the compression element is located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region. Instead, Weldon teaches sliding a wound treatment device 20 down tubular

portion 121 "until the distal end of the wound treating device 20 is generally in the vicinity of the opening or aperture in the artery wall F" (col. 12, li. 53-65; Fig. 22D and 22E). Applicants maintain that this fails to disclose "a predetermined distance proximal from the wall of the vessel" or defining a "tissue compression region."

Weldon also fails to disclose expanding the expansible tissue compression element above the blood vessel wall to apply pressure against subcutaneous tissue to compress the tissue over the puncture site (this step is facilitated by the compression element being located a predetermined distance proximal the vessel wall to define a tissue compression region). Neither does Weldon teach that when expanding the tissue compression element, the element is not in direct contact with the vessel wall. In contrast, Weldon teaches an inflatable means 32 that expands to retain the position of the clotting device 20. Weldon also teaches that the inflatable means 32 may be pressed against the aperture A in the artery F to assist the clotting agent in clotting the bleeding from aperture A (col. 6, li. 65 – col. 7, li. 20). Weldon also depicts the inflating means 32 as expanding against the outside surface of the vessel walls as a clotting agent is released, as shown below in Figures 22E and 22F. Nowhere does Weldon disclose expanding a compression element to apply pressure to compress subcutaneous tissue over the puncture without directly contacting the vessel wall, as recited in claim 1.



Even if the device of Weldon *could* perform the claimed method, such a finding would still not anticipate the claim under § 102. To support a showing of anticipation, "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." (emphasis added) *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939); see also *Ex parte Skinner,* 2 USPQ2d 1788 (BPAI 1986). Applicants maintain that there is no indication that the device of Weldon performs the claimed method, particularly since the methods described within include steps contrary to the method steps in claim 1 noted above.

Since Weldon fails to disclose each and every element of the method of claim 1, the cited reference cannot properly anticipate the claim. Therefore, Applicants respectfully request the rejection of claim 1 be withdrawn.

Dependent claims 5 and 8-11 ultimately depend from claim 1, which has been distinguished from the cited reference as discussed above. For at least the same reasons as claim 1, Applicants maintain that claim 5 and 8-11 are allowable over Weldon and respectfully request the rejections of claims 5 and 8-11 be withdrawn.

Claim Rejection – 35 USC § 103

Claims 3-4, 7, 14 and 17-21 were rejected under 35 USC 103(a) as allegedly unpatentable over Weldon (Office Action, pages 4-5). Such rejections are traversed in part and overcome in part for the following reasons.

Claims 3-4, 7, 14 and 17-21 ultimately depend from claim, which has been distinguished from Weldon as discussed above. Since Weldon fails to disclose at least the above bolded elements of amended claim 1, Applicants respectfully maintain that Weldon fails to establish *prima facie* obviousness as to claims 1 or any claim depending thereon.

Moreover, Weldon fails to disclose a reason for modifying the device or method of Weldon as required to perform the method of claim 1. Since Weldon does not teach using the balloon to apply pressure to compress subcutaneous tissue over the puncture site there would be no reason to locate a compression element a predetermined distance proximal of the vessel wall. This argument is further supported by the teaching in Weldon that the inflating means 32 may be pressed against the vessel wall (col. 7, li. 20). Although Weldon teaches that the treatment device 20 is inserted "until the distal end of the wound treating device 20 is generally in the

vicinity of the opening or aperture in the artery wall F" (col. 12, li. 53-65; Fig. 22D and 22E), Applicants maintain this is no way suggests that the compression element be positioned a predetermine distance proximal of the vessel wall, as recited in claim 1. As Weldon fails to disclose each and every element of claim 1, as well as a reason for modifying the reference as suggested by the Examiner, the Office Action has failed to establish *prima facie* obviousness with respect to claim 1 or any claim depending thereon. Therefore, Applicants respectfully request that the rejections of claims 3-4, 7, 14 and 17-21 be withdrawn.

Furthermore, Applicants maintain that claims 7-11 are further distinguishable from the cited reference. For example, claims 7-11 recite various alternative designs for the compression member. These shapes and designs, examples of which are illustrated in Figures 4A-7C, may allow forward compression of percutaneous tissue over the puncture site with the distal portion of the compression member (Paragraph [0045]). As Weldon discloses the inflatable means 32 as expanding to retain the position of the wound treatment device 20 and to restrict blood flow from the aperture in the vessel wall (col. 13, li. 3-4), it would be counterintuitive to shape the inflating means 32 as in any of claims 7-11, as this could frustrate one or more of the disclosed objectives of the inflatable means 32. Thus, Applicants maintain that claims 7-11 are allowable over Weldon for at least the same reasons as in claim 1, as well as on their own merits. Accordingly, Applicants respectfully request the rejections of claims 7-11 be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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